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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,033	11/27/2002	H. Michael Shepard	NB 2006.01; 060925-0601	2767

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FOLEY & LARDNER LLP
975 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
11/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/048,033	SHEPARD, H. MICHAEL	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 27, 2007 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,20,21,26,29,32-35 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20,21,34 and 35* is/are allowed.

6)☒ Claim(s) *17,26,29,32,33 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 November 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/30/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **1-16, 18 and 22-25** were previously cancelled, claims **19, 27-28, 30-31 and 36** are newly cancelled, claims **20, 26, 29, and 32-35** have been amended, the disclosure has not been further amended, and new claim **37** has been added as per the amendment filed August 27, 2007. One additional Information Disclosure Statement (1 IDS) filed August 30, 2007 has been received with copies of all cited non-US patent references and made of record. a

Claims **17, 20-21, 26, 29, 32-35 and 37** remain in the case.

Claims **17, 26, 29, 32-33 and 37** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for NB1011 in the treatment of a few specific neoplastic disease conditions, does not reasonably provide enablement for the vast array of neoplastic diseases encompassed by either claim **26** or claim **29** or the treatment of any disease condition with multiple active ingredients as specified sub-generically in the last two lines of claim **29** and specifically in claim **17**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The claims (**26 and 29**) are directed to the treatment of a large array of disease conditions with a large array of compounds, wherein all but one of proposed active ingredients have not been shown to have the claimed activity. In addition, there has been no showing that multiple active ingredients are effective or, if they are effective, how they are to be administered (e.g. together, alternatively, ?).

B. The nature of the invention: The invention is directed to the treatment of a wide variety of neoplastic diseases by the administration of compound NB1011 and analogues thereof alone or in combination with other compounds allegedly effective in combination therewith.

C. The state of the prior art: Aside from applicant's own work, there is no prior art which reads on the instant claims.

D. The level of one or ordinary skill: The level skill of the ordinary practitioner is very high in re administration of NB1011, but much lower when other active ingredients are at issue and very much lower when multiple active ingredients are specified in a method of treating a neoplastic disease condition.

E. The level of predictability in the art: The art area is predictable in the areas wherein NB1011 has been shown to have anti-neoplastic activity, but in other areas the predictability becomes indeterminate because of the absence of data.

F. The amount of direction provided by the inventor: The applicant has shown data only for the effective administration of NB1011 in a few disease treatments.

G. The existence of working examples: Working examples are limited to the administration of NB1011 alone in the treatment of only a few specific neoplastic disease conditions.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because only a single example (NB1011) and a few diseases effectively treated *in vitro* is an insufficient basis to extrapolate to the very large number of active ingredients and the large number of different disease conditions encompassed by the instant claims. The scope of the claims is excessive and needs to be very substantially narrowed because the small number of enabling exemplifications can not, and do not, adequately support claims of such a broad scope.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Examiner notes with appreciation the narrowing of the instant claims to identify some active ingredients and to limit the scope of other active ingredients. However, as noted above the scope of enabling subject matter is rather narrow and does not provide much room for broadly drafted claims.

Applicant argues that the instant claims are fully enabled because the claims are limited, and therefore do not apply to, the treatment of cancers wherein overexpression of thymidylate synthase occurs. Applicant acknowledges that only an appropriate variety colon cancer has been tested, but asserts that this isnot a proper basis for limitation of the claims to the specific embodiments. In the absence of evidence to support this request to extrapolate from the minimal exemplifications provided to all listed types of cancer defined by organ site and thymidylate synthase overexpression, examiner respectfully disagrees and respectfully requests any evidence applicant can muster to support this hypothesis.

In lieu of additional evidence, either as a declaration, or found in the prior art and cited, examiner has repeated the above rejection.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **17, 26, 29, 32-33 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-12*** of U. S. Patent No. **6,495,553**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 26, 29, 32-33 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***36-39*** of U. S. Patent No. **6,339,151**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 26, 29, 32-33 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-7*** of U. S. Patent No. **6,245,750**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 20-21, 26, 29, 32-35 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***56-84 and 86-89*** of co-pending Application No. **09/782,721** (for the PG Pubs version, see PTO-892 ref. **P1**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and the methods of treatment are overlapping with the instant claimed subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 20-21, 26, 29, 32-35 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***15-18, 21-23 and 27-50*** of co-pending Application No. **09/789,226**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and the methods of treatment are overlapping with the instant claimed subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 20-21, 26, 29, 32-35 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-36*** of co-pending Application No. **11/034,036**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and the methods of treatment are overlapping with the instant claimed subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 20-21, 26, 29, 32-35 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-18*** of co-pending Application No. **10/051,320** (for the PG PUBS version, see PTO-892 ref. **P3**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and the methods of treatment are overlapping with the instant claimed subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 20-21, 26, 29, 32-35 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1 and 53-83*** of co-pending Application No. **10/681,418**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant is referred to comments made in response following the last obviousness-type double patent rejection below.

Claims **17, 26, 29, 32-33 and 37** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-10*** of U. S. Patent No.

6,683,061 (PTO-892 ref. **AB**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and the methods of treatment are overlapping with the instant claimed subject matter.

Applicant's arguments filed August 27, 2007 have been fully considered but they are not persuasive.

Applicant has not effective addressed any of the above obviousness-type double patenting rejections by filing a Terminal Disclaimer but has requested deferral until allowable subject matter has been indicated. Therefore all of the above double patenting rejections have been maintained.

One or more of claims **17, 20-21, 26, 29, 32-35 and 37** of this application conflict with claims ***1-33*** of Application No. **10/119,927**, claims ***56-84 and 86-89*** of Application No. **09/782,721**, claims ***1-18*** of co-pending Application No. **10/051,320**, claims ***1 and 53-83*** of co-pending Application No. **10/681,418**, claims ***1-36*** of copending Application No. **11/034,036**, and claims ***15-18, 21-23 and 27-50*** of copending Application No. **09/789,226**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

Claims **20, 21 and 34-35** have been found allowable in view of applicant' argument and prior art submissions.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to

37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

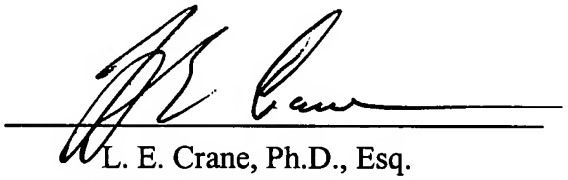
Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

LECrane:lec
11/26/2007



L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600